

SUPPLEMENT to K964528 BENZ-G 3X (hioxifilcon B) JAN. 15, 1997

6.0 SUMMARY of SAFETY AND EFFECTIVENESS

MAR 10 1997

I. General Information:

- A. Generic (USAN) Name: hioxifilcon B
- B. Device Trade Name: BENZ-G 3X (hioxifilcon B) Spherical and Toric Soft (Hydrophilic) Contact Lenses for Daily Wear in Clear and with a Blue Visibility Tint
- C. Sponsor's Name and Address: BENZ Research and Development, Inc.
6447 Parkland Drive
Sarasota, FL 24243
(941) 758-8256
- D. 510(k) Number: K964528

II. Indications

BENZ-G 3X Spherical (hioxifilcon B) soft (hydrophilic) contact lenses made from BENZ-G 3X (hioxifilcon B) optical blanks in clear or a blue visibility tint are indicated in daily wear for the correction of visual acuity in aphakic and/or non-aphakic persons with with non-diseased eyes. The Spherical lenses are available from +20.00 to - 20.00 Diopters for persons who have up to 1.50 Diopters of astigmatism where the astigmatism does not interfere with visual acuity.

BENZ-G 3X Toric (hioxifilcon B) soft (hydrophilic) contact lenses made from BENZ-G 3X (hioxifilcon B) optical blanks in clear or blue visibility tint are indicated in daily wear for the correction of visual acuity in aphakic and/or non-aphakic persons with with non-diseased eyes. The toric lenses are available from +20.00 to -20.00 Diopters and up to 4.50 Diopters of astigmatic correction.

The material, BENZ-G 3X (hioxifilcon B), is a non-ionic polymer that may be disinfected using either the heat (thermal) or the chemical (not heat) disinfection system.

III. Device Description

BENZ-G 3X (hioxifilcon B) Spherical or Toric is lathed into a soft (hydrophilic) contact lens which is a hemispherical shell. The Toric has a Toric Base Curve. The non-ionic material, hioxifilcon B is a copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydroxypropyl methacrylate (Glycerol Methacrylate, GMA). The copolymer consists of 52% BENZ-G 3X (hioxifilcon B) and 48% water by weight when immersed in normal saline solution buffered with sodium bicarbonate.

6.0 SUMMARY OF SAFETY AND EFFECTIVENESS

The lens BENZ-G 3X (hioxifilcon B) is made from BENZ-G 3X (hioxifilcon B) optical buttons. When the lens is hydrated and placed on the cornea it acts as a refracting medium to focus light rays on the retina.

BENZ-G 3X (hioxifilcon B) optical buttons with visibility tint were subjected to extraction studies and showed no identifiable evidence of tint pigment leeching.

IV. Alternative Practices or Procedures

Alternative practices or procedures are in the use of available prescription products Soft and RGP Contact Lenses and spectacles for the same indication.

V. Technical Summaries

A. Pre Clinical

1. Toxicology

Toxikon ran all pre-clinical studies necessary for review for Class II daily wear soft (hydrophilic) contact lenses. Results were within normal limits.

2. Microbiology

Relevant studies have been run and are included with this 510(k) notification. This includes autoclave validation.

3. Lens compatibility studies run by BENZ Research and Development included with this Notification in Section 6.3 "Lens Compatibility Studies"

Conclusion: Within Normal Limits

4. Lens Stability The Shelf life studies have been started by Metro Optics of Austin, Inc. and will be complete later in the year. The procedure is based on sample supplied by FDA in Guidance Document for 510(k) for Daily Wear Contact Lenses, May 1994. Study will be completed in late January 1997 to assure sterility to the one year duration. No product will be distributed until tests are complete and the FDA has approved manufacture and distribution.

5. Preservative Uptake Tests were run by ALCON and are included in this Notification in Sect 6.5 They fall within normal limits.

This application includes application for Heat and Chemical (Not Heat) disinfection as the polymer as the polymer is Non-ionic. In house tests showing that heat

6.0 SUMMARY OF SAFETY AND EFFECTIVENESS

has no injurious effect on the lenses made of this polymer. BENZ-G 3X studies are on file at BENZ R&D and are included with this supplement.

BENZ RESEARCH AND DEVELOPMENT, INC. will own the polymer BENZ-G 3X (hioxifilcon B) optical blanks in clear and with blue visibility tint and make the polymer available to any contact lens laboratory that will apply to the FDA through 510(k) Notification and be approved to manufacture and distribute soft (hydrophilic) contact lenses made from BENZ-G 3X.

This summary of safety and effectiveness enclosed covers the hioxifilcon B lathe-cut lens made by BENZ Research and Development, Inc.

A favorable recommendation from the FDA for the BENZ-G 3X (hioxifilcon B) Spherical and Toric Contact Lenses made from BENZ-G 3X (hioxifilcon B) in clear or with blue visibility Tint for daily wear use is anticipated. We feel that a review of notification will show that this polymer is close enough to the approved BENZ-G 55 (5X) (hioxifilcon A) (48% water as opposed to 58% water). The BENZ-G 55 (5X) was both safe and effective for its intended purpose of a daily wear contact lens.

Should additional information be desired, please contact Wally Stirling, South East Regulatory Associates, Inc. 770-475-1668.